K 121467

Eurotrol B.V.
Eurotrol Hct Control and epoc Hematocrit Verification Fluids
May 10, 2013

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510(k) Summary

Submitter: Eurotrol B.V.
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Date of Preparation: May 10, 2013

Proprietary Names: Eurotrol Hct Control and epoc® Hematocrit Verification Fluids

Classification Name: Hematocrit control, (21 CFR 864.8625, Product Code GLK)

Common Name: Eurotrol Hematocrit Control

Equivalent to: RNA Medical QC 900 Hematocrit Control (K955630)

Substantial Equivalence
Eurotrol Hematocrit Control is substantially equivalent in function, safety and efficacy to currently marketed devices produced by Bionostics.

Comparison of Eurotrol Hematocrit Control to predicate device for substantial equivalency:

	New Device	**Predicate Device**
	Eurotrol Hct Control and epoc®Hematocrit Verification Fluids	**RNA Medical QC 900 Hematocrit Control**
510(k), date		K955630, 03/01/1996
Number of levels	5	5
Analytes	Hematocrit (Conductivity)	Hematocrit (Conductivity)
Container	Clear glass ampules	Clear glass ampules
Filling Volume	2,5 mL	1,7 mL
Color	Clear	Clear
Storage temperature	2 - 30°C/35 - 86°F	2 - 25°C/35 - 77°F
Matrix/Materials	Eurotrol Hematocrit Control is prepared using pure chemicals in a physiologically buffered matrix. Different concentrations provide five distinct Hct levels (conductivity), simulating clinically significant ranges of Hematocrit.	QC 900 is a buffered aqueous solution containing electrolytes and non-conductive ingredients. This product contains no red cells and no human or biological materials.

Description of the new device

Eurotrol Hct Control and epoc® Hematocrit Verification Fluids are assayed hematocrit reference materials, to verify the precision and accuracy of the epoc® Blood Analysis System, manufactured by Epocal Inc., Ottawa, ON K1G3P5, Canada, as cleared by FDA, K061597. Eurotrol Hematocrit Control was designed to test the following analytes: Hematocrit.

Eurotrol Hct Control and epoc® Hematocrit Verification Fluids electrolyte solutions with conductivity at five levels appropriate to simulate clinically relevant hematocrit concentrations useful to evaluate the measurement of the epoc Blood Analysis System.

Depending the sales unit, 10 ampules of the same level are packed in a carton box for Eurotrol Hct Control, or 5 ampules, 1 ampule per level, are packed in a carton box for epoc®Hematocrit Verification Fluids. A product insert with Intended Use is inserted in each product box.

The assigned values of each batch are printed on a value sheet as available from the Epocal website: http://www.epocal.com/doc_library.html

Intended Use

epoc® Hematocrit Verification Fluids is an assayed hematocrit reference material, to verify the precision and accuracy of the epoc® Blood Analysis System for the measurement of hematocrit.

Eurotrol Hct Control is an assayed hematocrit reference material, to verify the precision and accuracy of the epoc® Blood Analysis System for the measurement of hematocrit.

Eurotrol Hct Control and epoc® Hematocrit Verification Fluids are for professional use only.

Technological Characteristics

Eurotrol Hct Control and epoc® Hematocrit Verification Fluids are filled in 3 mL clear glass ampules. Each ampule contains 2.5 mL product.

This material consists of an Aqueous buffered solution of water and electrolytes in 5 different levels.

The stability of Eurotrol Hematocrit Control is 12 months.

Summary of non-clinical tests submitted with the premarket notification for the device.
Tests were conducted to verify specific performance requirements:
a) Real-time evaluation of the products to support stability.
b) Test precision

Summary of clinical tests submitted with the premarket notification for the device.
N/A

Conclusions drawn from the clinical and non-clinical trials.
Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

PAUL B. P. KOOIJMANS
REGULATORY AFFAIRS MANAGER
EUROTROL B.V.
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THE NETHERLANDS

May 10, 2013

Re: K121467
Trade/Device Name: Eurotrol Hct Control and epoc® Hematocrit Verification Fluids
Regulation Number: 21 CFR 864.8625
Regulation Name: Hematology quality control mixture
Regulatory Class: II
Product Code: GLK
Dated: April 19, 2013
Received: April 29, 2013

Dear Mr. Kooijmans:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Reena Philip -S

for

Maria M. Chan
Director, Division of Immunology and Hematology
Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k121467

Device Name: Eurotrol Hct Control and epoc® Hematocrit Verification Fluids

Indications For Use:

Eurotrol Hct Control

Eurotrol Hct Control is an assayed hematocrit reference material, to verify the precision and accuracy of the epoc® Blood Analysis System for the measurement of hematocrit.
Eurotrol Hct Control is for in vitro diagnostic use only.

epoc® Hematocrit Verification Fluids
epoc® Hematocrit Verification Fluids is an assayed hematocrit reference material, to verify the precision and accuracy of the epoc® Blood Analysis System for the measurement of hematocrit.

epoc® Hematocrit Verification Fluids is for in vitro diagnostic use only.

Prescription Use _X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of In Vitro Diagnostics and Radiological Health (OIR)

Maria M. Chan -S

Division Sign-Off
Office of In Vitro Diagnostics and Radiological Health